

SUBCHAPTER 14. THERAPEUTIC INSTALLATIONS

7:28-14.1 Scope

- (a) This subchapter covers therapeutic installations used in the healing arts. These therapeutic installations include x-ray, accelerator and teletherapy installations. No registrant shall operate or permit the operation of therapeutic equipment used in the healing arts unless the equipment and installation meet the applicable requirements of this subchapter.

7:28-14.2 Definitions

The following words and terms, when used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise.

“Applicator” means a structure which determines the extent of the treatment field at a given distance from the virtual source and which may or may not incorporate the beam limiting device.

“Beam interceptor” means a device located on the central axis of the primary beam whose purpose is to substantially attenuate the beam so that the room shielding requirements may be reduced.

“Beam limiting device” means a device which provides a means to restrict the dimensions of the radiation field and which is an integral part of the equipment.

“Beam monitoring system” means a system designed to detect and measure the radiation present in the useful beam.

“Beam scattering filter” means a filter used to scatter a beam of electrons.

“Central axis of the beam” means a line passing through the virtual source and the center of the plane figure formed by the edge of the final beam limiting device.

“Contact therapy system” means an x-ray system used for therapy not capable of operating above 60 kVp and with a source distance less than or equal to five centimeters.

“Department” means the New Jersey Department of Environmental Protection.

“Dose monitoring system” means a system of devices for the detection, measurement, and display of dose information for the useful beam.

“Dose monitor unit” means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

“Field flattening filter” means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

“Field size” means the projection on a plane perpendicular to the beam axis, of the distal end of the collimator as seen from the front center of the source.

“Full beam detector” means a radiation detector of such size that the total cross section of the maximum-size useful beam is intercepted.

“Gantry” means that part of the system supporting and allowing possible movements of the radiation head.

“Interlock” means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

“Interruption of irradiation” means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

“Isocenter” means a fixed point in space located at the center of the smallest sphere through which the central axis of the beam pass.

“Leakage radiation” means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

“Moving beam therapy” means radiation therapy with relative movement of the useful beam and the patient during irradiation.

“Normal treatment distance” means:

1. For electron irradiation, the nominal source to surface distance along the central axis of the useful beam, specified by the manufacturer for the applicator;
2. For x-ray irradiation, the nominal source to isocenter distance along the central axis of the useful beam; and
3. For non-isocentric equipment, this distance shall be specified by the manufacturer.

“Phantom” means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

“Primary dose monitoring system” means a system which will monitor the quantity of radiation produced during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

“Qualified radiological physicist” means a person who holds at least a bachelor’s degree in one of the physical sciences and who is certified by the American Board of Radiology either in radiological physics, x- and gamma ray physics or therapeutic radiological physics, is eligible for such certification, or has equivalent training and experience.

1. “Equivalent training and experience” means a person has:

- i. A bachelor’s degree in physical sciences and three years full time experience working under the direction of a physicist certified by the American Board of Radiology;
- ii. A doctorate or master’s degree in physical science and two years such experience; or

- iii. A doctorate or master's degree in radiological or medical physics and two years of full-time, post-doctoral training with clinical experience.

"Registrant" means the person required to register with the Department pursuant to N.J.A.C. 7:28-3.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

"Spot check" means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.

"Stationary beam therapy" means radiation therapy without relative movement of the useful beam and the patient during irradiation.

"Target" means that part of a radiation-producing device used to intercept a beam of accelerated particles and cause emission of other radiation.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Transmission detector" means a radiation detector through which the useful beam or part of the useful beam passes.

"Traceable to national standards" means a dosimetry system calibrated by the National Bureau of Standards (NBS) or calibrated in a beam which has been standardized by a transfer-grade ionization chamber having a NBS calibration.

"Treatment field" means the area of the patient's skin which is to be irradiated.

"Virtual source" means a point from which radiation appears to originate.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

7:28-14.3 Therapeutic x-ray systems with energies less than one MeV

(a) Equipment requirements for therapeutic x-ray systems with energies less than one MeV are as follows:

1. Leakage radiation shall be measured under conditions which provide maximum leakage radiation, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system. Compliance shall be determined by measurements averaged over an area of 100 square centimeters. Measurement shall be performed at installation and whenever the tube is changed. Measurement shall be performed at least once every five years;

- i. For Contact Therapy Systems, leakage radiation shall not exceed 100 milliroentgens in one hour at five centimeters from the surface of the tube housing assembly;
 - ii. For 0-150 kVp Systems which are installed prior to October 1, 1987, leakage radiation shall not exceed one roentgen in one hour at one meter from the target;
 - iii. For 0-150 kVp Systems which are installed on or after October 1, 1987, leakage radiation shall not exceed 100 milliroentgens in one hour at one meter from the target;
 - iv. For 151 to 500 kVp Systems the leakage radiation shall not exceed one roentgen in one hour at one meter from the target;
 - v. For 501 to 999 kVp Systems the leakage radiation at a distance of one meter from the target shall not exceed 0.1 percent of the useful beam exposure rate at one meter from the target; and
 - vi. Records of leakage radiation shall be maintained at the facility for at least five years and shall be made available for inspection by the Department.
2. Beam limiting devices for equipment installed on or after October 1, 1987 shall transmit no more than one percent of the useful beam, for the portion of the beam which is to be attenuated by the beam limiting device, when the equipment is operating at maximum kVp and with maximum filtration. Measurements shall be made at a distance of one meter from the beam limiting device and in a plane perpendicular to the central axis of the beam. For equipment installed before October 1, 1987, transmissions shall not exceed five percent of the useful beam;
3. The filter system shall be so designed that:
 - i. It will minimize the possibility of error in filter selection;
 - ii. Filters cannot be accidentally displaced from the useful beam at any possible tube orientation;
 - iii. Each filter is marked as to its material of construction and its thickness or wedge angle for wedge filters;
 - iv. It shall be possible for the operator to determine the presence or absence of any filter in the useful beam when the operator is at the control panel, either by display at the control panel or by direct observation;

- v. For equipment installed prior to October 1, 1987, the radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under any operating conditions; and
 - vi. For equipment listed on or after October 1, 1987, the radiation from the filter slot shall not exceed the leakage radiation specified in (a)1 above.
- 4. A means shall be provided to immobilize the tube housing assembly during stationary treatments;
- 5. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters, and such marking shall be readily accessible for use during calibration procedures;
- 6. Equipment employing Beryllium or other low-filtration windows shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use;
- 7. Radiotherapy systems of greater than 150 kVp installed on or after October 1, 1987 shall be provided with a beam monitor system which shall:
 - i. Include a radiation detector which is placed on the patient side of any fixed added filters other than a wedge filter;
 - ii. Have the radiation detector interlocked to prevent its incorrect positioning in the useful beam;
 - iii. Not allow irradiation until a pre-selected value of exposure or pre-selected number of dose monitor units has been made at the treatment control panel;
or dose monitor units has been reached;
 - v. Be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
 - vi. Have a display at the control panel, reading in roentgens, or coulombs per kilogram from which the dose at a reference point in the treatment volume can be calculated;

(1) The reading shall be maintained in the display at the control panel until intentionally reset to zero; and
 - vii. Have a control panel display which does not have scale multiplying factors and utilizes a design such that an increasing dose is displayed by increasing numbers.

8. The following are the equipment requirements for timer systems:
 - i. A timer system shall be provided which has a display at the treatment control panel. It shall be graduated in minutes and seconds and/or fractions of minutes. It shall have a pre-set time selector. For equipment installed on or after October 1, 1987, it shall also have an elapsed time indicator;
 - ii. The timer shall terminate irradiation when a pre-selected time has elapsed;
 - iii. The timer shall permit pre-setting and determination of exposure times to an accuracy of one second or less;
 - iv. The timer shall not permit an exposure if set at zero;
 - v. When patient irradiation is controlled by a shutter mechanism the timer shall not begin to run until the shutter is opened;
 - vi. Equipment installed on or after October 1, 1987 shall have an elapsed-time indicator which is activated when radiation is emitted and retains its reading after irradiation is interrupted or terminated; and
 - vii. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the pre-set time selector through zero time.
9. In addition to the control panel displays required in other provisions of this subsection, the control panel shall have:
 - i. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
 - ii. An indication of whether x-rays are being produced;
 - iii. Means for indicating kVp and x-ray tube current; and
 - iv. The means for terminating an exposure at any time.
10. There shall be a means of determining the source-to-patient distance to within 10 percent or one centimeter, whichever is smaller; and
11. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds, the entire useful beam shall be attenuated automatically by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition:
 - i. After the unit is at operating parameters, the shutter shall be controlled electrically from the control panel by the operator; and
 - ii. An indication of shutter position shall appear at the control panel.

(b) In addition to shielding adequate to meet the requirements of N.J.A.C. 7:28-5 and 6, the treatment room design and shielding requirements for systems capable of operating above 50 kVp, shall be the following:

1. There shall be warning lights in treatment rooms to which access is possible through more than one entrance. The warning lights shall be placed in readily observable positions near the outside of all access doors and shall indicate when the useful beam is "on";
2. There shall be means for two-way aural communication between the patient and the operator at the control panel at all times when the system is in operation;
3. A window, mirror, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means (for example, television), a secondary viewing system shall be available for use in the event of failure of the primary viewing system;
4. Treatment rooms which contain an x-ray system capable of operating above 150 kVp shall meet the following additional requirements:
 - i. All required shielding, except for any beam interceptor, shall be provided by fixed barriers;
 - ii. The control panel shall be outside the treatment room;
 - iii. All entrance doors of the treatment room shall be electrically connected to the control panel in such a way that x-ray production cannot occur unless all doors are closed;
 - iv. When any entrance door of the treatment room is opened while the x-ray tube is activated, x-ray production shall terminate within one second; and
 - v. After the radiation output of the x-ray tube has been terminated by the opening of any door of the treatment room, it shall be possible to restore the x-ray system to full operation only upon closing the door, and subsequently, reinitiating the exposure at the control panel.

(c) The following are the calibration requirements for therapeutic x-ray systems with energies less than one MeV:

1. System calibrations shall be performed before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12

months and after any change which might significantly alter the calibration or other characteristic of the therapy beam;

2. The calibration of the radiation output of the x-ray system shall be performed by a qualified radiological physicist;
 3. Calibration of the radiation output of an x-ray system shall be performed with an instrument whose calibration shall be directly traceable to a national standard and which shall have been calibrated within the preceding three years;
 4. The calibration shall be such that the dose at a reference point in soft tissue can be calculated to within ± 5 percent;
 5. The calibration of the x-ray system shall include, but not be limited to, the following determinations;
 - i. Verification that the x-ray system is operating in compliance with the radiological design specifications;
 - ii. The exposure rates for each combination of field size, technique factors, filter, and treatment distance used;
 - iii. The congruence between the radiation field and the field indicated by the localizing device if such device is present; and
 - iv. The uniformity of the radiation field symmetry for representative field sizes used.
 6. Records of calibration performed pursuant to 1 above shall be maintained by the registrant and made available for inspection by the Department for five years after completion of the calibration.
- (d) Spot checks shall be performed on therapeutic x-ray systems with energies greater than 0.018 MeV and less than one MeV and shall meet the following requirements:
1. The qualified radiological physicist will determine those parameters to be spot-checked and the procedure to be used when performing those spot checks. The spot check procedure shall be in writing and specify the frequency at which tests or measurements are to be performed, not to exceed one month, and the acceptable tolerance for each parameter measured in the spot-check. A qualified radiological physicist need not actually perform the spot-check measurement. If a qualified radiological physicist does not perform the spot-check measurement, the results of the spot-check measurement shall be reviewed by a qualified radiological physicist within 15 days;

2. The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure;
 3. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot check procedures, the system shall be recalibrated;
 4. The cause for a parameter exceeding tolerances set by the qualified radiological physicist shall be promptly investigated and corrected before the system is used for patient irradiation; and
 5. Records of spot-check measurements shall be maintained by the registrant and made available for inspection by the Department for a period of five years following such measurement.
- (e) The following procedures shall be followed when operating therapeutic x-ray systems with energies less than one MeV:
1. A therapeutic x-ray system shall not be left unattended unless the system is secured against unauthorized use;
 2. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier meeting the requirements of N.J.A.C. 7:28-6. No individual other than the patient shall be in the treatment room during exposure when the kVp exceeds 50;
 3. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used; and
 4. Except for contact therapy devices, the tube housing assembly shall not be held by an individual during exposure.
- (f) The x-ray system shall not be used in the administration of radiation therapy unless the requirements of this section have been met.

Correction: Therapeutic x-ray systems with energies less than one MeV for 0-150 kVp systems which are installed prior to October instead of January.

See: 19 N.J.R. 1917(c).

7:28-14.4 Therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above

- (a) The following are the equipment requirements related to leakage radiation to the patient area:

1. Leakage radiation shall be measured under conditions producing maximum leakage radiation and shall be reported as absorbed dose in rads or grays in water. For equipment installed on or after October 1, 1987, measurements shall include x-rays, electrons and neutrons. For equipment incapable of operating at energies greater than 10 MeV, measurements shall exclude neutrons. For equipment installed before October 1, 1987, measurements shall exclude neutrons. The leakage radiation shall be measured in a plane perpendicular to the central axis of the beam located at the normal treatment distance or passing through the isocenter. The leakage radiation at any point on this plane outside the useful beam but within two meters of the central axis of the beam shall not exceed 0.1 percent of the maximum radiation of the useful beam, measured at the point of intersection of the central axis and the plane;
 2. Measurements for leakage radiation shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. For equipment installed on or after October 1, 1987, measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 400 square centimeters. For equipment incapable of operating at energies greater than 10 MeV, measurements shall exclude neutrons. For equipment installed before October 1, 1987, measurements shall exclude neutrons;
 3. For each system the registrant shall determine, or obtain from the manufacturer, the amount of leakage radiation at the positions specified in 1 above. Records of leakage radiation shall be maintained at the facility for inspection by the Department.
- (b) The following are the equipment requirements for leakage radiation outside the patient area:
1. Except in the area specified in (a) above as the patient area, the x-ray leakage measured as absorbed dose in rads or grays in water, at any location averaged over 100 square centimeters one meter from the path of the charged particles before they strike the target or the window, shall not exceed 0.1 percent of the maximum absorbed dose in the circular plane specified in (a) above;
 2. Except in the area specified in (a) above as the patient area, neutron leakage measured as absorbed dose in rads or grays in water, at any point one meter from the path of the charged particles before they strike the target or the window, shall not exceed 0.5 percent of the maximum absorbed dose in the circular plane specified in (a) above;
 3. The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 1 and 2 above for

specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. For equipment installed on or after October 1, 1987, neutron measurement shall be averaged over an area up to, but not exceeding, 400 square centimeters. For equipment incapable of operating at energies greater than 10 MeV, measurements shall include neutrons. For equipment installed prior to October 1, 1987, measurement of neutrons shall be excluded.

(c) The following are the equipment requirements for beam limiting devices:

1. For equipment installed on or after October 1, 1987, adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than one percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement; and
2. For equipment installed prior to October 1, 1987, the beam limiting device shall meet the requirements of (a)1 above except that such device shall transmit no more than two percent of the useful beam.

(d) The following are the equipment requirements for filters:

1. If the absorbed dose rate information required by (p) below relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools;
2. In systems installed on or after October 1, 1987, which utilize a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters:
 - i. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - ii. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - iii. A display shall be provided at the treatment control panel showing the filter in use;
 - iv. Each filter which is removable from the system without the use of tools shall be clearly marked with an identification number and accompanying documents shall contain a corresponding drawing or other description of the filter, showing dimensions and materials. The identification number

shall appear on the wedge filter as well as on its tray. The identification number shall be referable to wedge angle and wedge factor; and

- v. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
3. The only filter requirement for equipment installed prior to October 1, 1987 shall be that required by (d)2iv above.
- (e) Beam quality data sufficient to assure that the following beam quality requirements are met shall be determined or obtained from the manufacturer by the registrant:
1. For radiotherapy systems capable of electron beam therapy the absorbed dose in water resulting from x-rays in a useful electron beam shall be determined at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons. This shall not exceed the values stated in the following table. Linear interpolation shall be used for values not stated;

TABLE

Maximum Energy of Electron
X-Ray absorbed Dose as a Fraction

| Beam in MeV | of Maximum Absorbed Dose |
|-------------|--------------------------|
| 1 | 0.03 |
| 15 | 0.05 |
| 35 | 0.10 |
| 50 | 0.20 |

2. Compliance with 1 above shall be determined using:
 - i. A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
 - ii. The largest field size available which does not exceed 15 centimeters by 15 centimeters; and
 - iii. A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.
3. The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall be measured at intervals not to exceed 12

months and the results of such measurements shall be maintained with the records of calibration;

4. The measurements required by (e)3 above shall conform to the following requirements:
 - i. Measurements shall be made within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;
 - ii. Measurements shall be made using a phantom whose size and placement meet the requirements of 2iii above;
 - iii. Measurements shall be made after removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and
 - iv. Measurements shall be made over the range of field sizes clinically used.
 5. The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose due to stray neutrons in the useful beam for specified operating conditions.
- (f) All therapy systems shall be provided with radiation detectors in the radiation head.
1. Equipment installed on or after October 1, 1987 shall be provided with at least two radiation detectors. The detectors shall be incorporated into two monitoring systems arranged either as a primary/primary combination or as a primary/secondary combination;
 2. Equipment installed prior to October 1, 1987 shall be provided with at least one radiation detector. This detector shall be incorporated into a primary system. Failure of this detector shall automatically cause the beam to be terminated; and
 3. Each detector and system into which the detector is incorporated shall meet the following requirements:
 - i. Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning;
 - ii. Each detector shall be capable of independently monitoring and controlling the useful beam;

- iii. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated;
- iv. For equipment installed on or after October 1, 1987, the primary dose monitoring system shall have a full beam transmission detector which is placed on the patient side of any fixed added filters other than a wedge filter;
- v. For equipment installed on or after October 1, 1987, the design of the dose monitoring system of (f)3iii above shall assure that:
 - (1) The malfunctioning of one system shall not affect the correct functioning of the second system; and
 - (2) The failure of any element which may be common to both systems shall terminate the useful beam.
- vi. Each dose monitoring system shall have a legible display at the treatment control panel. Each display shall:
 - (1) Maintain a reading until intentionally reset to zero;
 - (2) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under all normal conditions of use or foreseeable failures; and
 - (3) In equipment installed on or after October 1, 1987 have only one scale and no scale multiplying factors when employed for routine therapy. A scale multiplying factor may be applied to the regularly used accumulated dose indicator when used in conjunction with special treatment modes which use higher than normal dose rates and require specially safeguarded operating procedures to initiate.
- vii. In the event of power failure, the dose monitoring information required in 3vi above displayed at the control panel at the time of failure shall be retrievable in at least one system.

(g) Beam symmetry requirements are the following:

- 1. For equipment installed on or after October 1, 1987 and which is inherently capable of producing useful beams with asymmetry exceeding five percent, at least four different parts of the radiation beam shall be monitored before the beam passes through the beam limiting device. If the difference in dose rates between any two of these different parts exceeds five percent an indication of

this condition is to be made at the control panel and the irradiation shall automatically terminate; and

2. The beam symmetry requirements of 1 above shall be met if the user can demonstrate to the satisfaction of the Department that adequate fail-safe protection against the beam asymmetry is incorporated into the inherent design of the accelerator.
- (h) Equipment requirements for the selection and display of dose monitor units are the following:
1. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel;
 2. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation; and
 3. After termination of irradiation, it shall be necessary to manually cycle the pre-selected dose monitor units through zero or manually change at least one digit on the dose monitor units selector before treatment can be initiated.
- (i) Equipment requirements for termination of irradiation by the dose monitoring system are the following:
1. Each of the required monitoring systems shall be capable of terminating irradiation independently;
 2. Each primary dose monitoring system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;
 3. Each secondary dose monitoring system shall terminate irradiation when 10 percent or 30 monitor units above the pre-selected number of dose monitor units has been detected by the system;
 4. For equipment installed on or after October 1, 1987, the indicator on the control panel shall show which monitoring system has terminated the beam.
- (j) Interruption switches shall be provided which make it possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.

(k) Termination switches shall be provided at the operator's position at the treatment control panel, which make it possible to terminate irradiation and equipment movements, or to go from an interruption condition to termination condition.

(l) The following are the equipment requirements for timer systems:

1. A timer system shall be provided which has a display at the treatment control panel. It shall be graduated in minutes and seconds and/or fractions of minutes. It shall have a pre-set time selector and an elapsed time indicator;
2. The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems fail to do so;
3. The timer shall not permit an exposure if set at zero;
4. There shall be an elapsed-time indicator which is activated when radiation is emitted and which retains its reading after irradiation is interrupted or terminated; and
5. After termination of irradiation on delivery of the present dose, it shall be necessary to manually change at least one digit on the pre-set time control before treatment can be re-initiated.

(m) Equipment capable of both x-ray therapy and electron therapy shall have the following equipment requirements for selection of radiation type:

1. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel;
2. An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected, except as noted in 4 below;
3. An interlock system shall be provided to prevent irradiation if any operations selected in the treatment room do not agree with the operations selected at the treatment control panel;
4. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted except to obtain a port film and to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
5. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

(n) The following are the equipment requirements for the selection of energy for equipment capable of generating radiation beams of different energies:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
 2. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;
 3. The nominal energy selected shall be displayed at the treatment control panel before and during irradiation; and
 4. For equipment installed on or after October 1, 1987, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than plus or minus five percent or plus or minus 2 MeV, whichever is smaller, from the selected nominal energy.
- (o) The following are the equipment requirements for selection of mode of therapy for equipment capable of both stationary beam therapy and moving beam therapy:
1. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel;
 2. An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected;
 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;
 4. An interlock system shall be provided to interrupt irradiation if the movement stops during moving beam therapy;
 5. Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained; and
 6. The mode of operation shall be displayed at the treatment control panel.
- (p) Equipment installed on or after October 1, 1987, shall be provided with a system from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in (f) above may form part of this system. In addition, the quotient of the number of dose monitor units by time shall be displayed at the treatment control panel.

- (q) The registrant shall determine, or obtain from the manufacturer, the location of the following with reference to an accessible point on the radiation head and under all possible orientations of the useful beam:
1. The x-ray target or the virtual source of x-rays; and
 2. The electron window, the scattering foil, or the virtual source of electrons.
- (r) When pre-selection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.
- (s) Shadow trays shall be designed to minimize patient entrance skin dose consistent with achieving their primary purpose of safely supporting beam-modifying accessories while transmitting the light field.
- (t) The following are the facility and shielding requirements for therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above:
1. The systems shall have shielding adequate to meet the requirements of N.J.A.C. 7:28-5 and 6;
 2. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers;
 3. The treatment control panel shall be located outside the treatment room;
 4. Windows, mirrors, closed-circuit television, or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. When the primary viewing system is by electronic means (for example, television), a secondary viewing system shall be provided for use in the event of failure of the primary system;
 5. Provision shall be made for two-way aural communication between the patient and the operator at the treatment control panel;
 6. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors which will indicate when the useful beam is "on";
 7. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall only be possible to restore the machine to operation by closing the door and reinitiating exposure by manual action at the control panel; and

8. At least one "Panic" emergency shut-off button shall be located in the treatment room and one by the control panel. The "Panic" button shall be clearly visible, easily accessible and be capable of immediately terminating machine operation.
- (u) The following are the calibration requirements for therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above:
1. The calibration of systems shall be performed before the system is first used for irradiation of a patient, and thereafter at time intervals which do not exceed 12 months and after any change which might, in the opinion of the qualified radiological physicist, significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam;
 2. The calibration shall be performed with an established calibration protocol which meets or exceeds the requirements set by the American Association of Physicists in Medicine;
 3. The calibration shall be performed by a qualified radiological physicist;
 4. The calibration shall be performed with a dosimetry system whose calibration shall be directly traceable to a national standard and which shall have been calibrated within the preceding three years;
 5. The calibration shall be such that the dose at a reference point in soft tissue may be calculated within plus or minus 5 percent;
 6. The full calibration of the therapy beam shall include, but not be limited to, the following determinations:
 - i. Verification that the equipment is operating in compliance with the design specifications for accuracy of the light localizer, the side light and backpointer alignment with the isocenter;
 - ii. Verification that the equipment is operating in compliance with the design specifications for acceptable variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths;
 - iii. The absorbed dose rate at representative depths in a phantom for the range of field sizes used for each effective energy, and for representative distances used for radiation therapy;
 - iv. The congruence between the radiation field and the field indicated by the localizing device;

- v. The uniformity of the radiation field and its dependency upon the direction of the useful beam;
 - vi. Verification of depth-dose data and isodose curves applicable to the specific machine; and
 - vii. Verification of the applicability and transmission factors of all accessories such as wedges, shadow trays, compensators, etc.
 - 7. Records of the calibration performed pursuant to 1 above shall be maintained by the registrant and made available for inspection by the Department for five years after completion of the calibration; and
 - 8. A copy of the latest full calibration shall be available for calculating patient treatment parameters.
- (v) Spot checks meeting the following requirements shall be performed on all therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above:
- 1. The qualified radiological physicist will determine those parameters to be spot-checked and the procedure to be used when performing those spot checks. The spot-check procedure shall be in writing and shall specify the frequency at which tests or measurements are to be performed, not to exceed one month, and the acceptable tolerance for each parameter measured in the spot-check. A qualified radiological physicist need not actually perform the spot-check measurement. If a qualified radiological physicist does not perform the spot-check measurement, the results of the spot-check measurement shall be reviewed by a qualified radiological physicist within 15 days;
 - 2. The measurements taken during spot-checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure;
 - 3. The cause for a parameter exceeding tolerances set by the qualified radiological physicist shall be promptly investigated and corrected before the system is used for patient irradiation;
 - 4. Whenever a spot-check indicates a significant change in the operating characteristics of a system, as specified in the spot-check procedures, the system shall be recalibrated as required in (u) above; and

5. Records of spot-check measurements performed shall be maintained by the registrant for a period of five years and made available for inspection by the Department.

(w) Operating procedures for therapeutic x-ray and therapeutic accelerator installations with energies of one MeV and above are as follows:

1. Therapeutic systems shall not be left unattended unless the system is secured against unauthorized use;
2. No individual other than the patient shall be in the treatment room during treatment of a patient;
3. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and
4. The system shall not be used in the administration of radiation therapy unless the requirements of (u) and (v) above have been met.